CLINICAL ALERT: DIALYSATE

May 29, 2012

Source: www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm305477.htm

Summary:

The FDA issued an alert on May 25, 2012, reminding dialysis care providers about acetate, acetic acid and/or citrate levels in dialysate concentrates and the need to consider the impact of these substances when ordering or administering the patient's dialysate prescription.

When metabolized, these potential sources of alkali can contribute to elevated bicarbonate levels in patients undergoing hemodialysis. This can contribute to metabolic alkalosis, which is a significant risk factor associated with cardiopulmonary arrest, low blood pressure, hypokalemia, hypoxemia, hypercapnia, and cardiac arrhythmia.

Health care professionals may not be aware that the dialysate acid concentrate can contain acetic acid, acetate or citrate, and that these substances can be converted in the body to bicarbonate, potentially contributing to metabolic alkalosis. These substances typically are found in acid concentrate in amounts ranging from 1.5 to 8 mEq/L. This potential exists for all currently marketed dialysate concentrate products containing acetate, acetic acid, or citrate.

Recommendations for Health Care Providers:

- Be aware that metabolic alkalosis (pre-dialysis serum bicarbonate levels > or = to 27 mEq/L) has been associated with a higher risk of death in hemodialysis patients.
- Before writing the bicarbonate component of the dialysate prescription or using dialysate concentrates:
  - Review the dialysate acid concentrate labeling for the specific concentrate that you prescribe or use to determine the components that can contribute to the patient's bicarbonate level. The levels of acetate, citrate and/or acetic acid vary by product and manufacturer.
  - Be sure to understand how your specific hemodialysis device proportions (mixes) the acid and base concentrates.
  - Be aware that some dialysate acid concentrates contain acetate, citrate and acetic acid level combinations up to 8 mEq/L, and some products may contain both acetate and acetic acid.
- Discuss laboratory results with your patients as appropriate.

Reporting Problems to the FDA:

If you suspect a problem with Dialysate Concentrates, you can file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program. Health care personnel employed by facilities that are subject to the FDA’s user facility reporting requirements should follow the reporting procedures established by their facilities.

Contact Information:

If you have questions about the FDA Alert, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.